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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,500	06/19/2006	Toyohiko Takushige	SHOBA5.001APC	3693

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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11/17/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
efiling@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/583,500	Applicant(s) TAKUSHIGE ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Action mailed November 9, 2010 has been vacated and replaced with this Supplemental Non-Final.

Applicants' arguments in the Request for Continued Examination, filed June 14, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 - Obviousness

Claims 7-8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Vermeer (US Patent 5,624,906). The rejection is maintained.

Applicant's Arguments

Applicant argues claim 7 requires all of the compounds recited. Vermeer merely lists the claimed ingredients as a part of his list having over 30 ingredients and does not teach the specific combination recited in Claim 7. Further, Vermeer teaches "Typical levels of humectants are from 0% to about 80%", which indicates none of the listed ingredients are essential. Thus, the cited reference does not teach all the claim limitations, and does not give any reason to pick the claimed ingredients. Moreover, the claimed combination provides new advantages which further evidence the nonobviousness of the claimed invention.

Applicant has previously presented Declaration under 37 C.F.R. § 132 to show data indicating the advantages of the claimed composition, however the Examiner asserted the data is insufficient. As Claim 7 does not limit the amount of each component, the amount should not be an issue. Nevertheless, Applicant submits another Declaration herewith to provide the required information.

Examiner's Response

Although the reference discloses about 30 ingredients, as previously submitted, most of these ingredients are polyethylene glycols. Further the reference teaches mixtures of these ingredients, thereby suggesting the instantly claimed combination. Therefore the reference does teach all the claim limitation and gives reason to pick the claimed ingredients because the reference suggests using mixtures of the disclosed ingredients. The reference claims also recite the polyethylene glycol and propylene

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glycol, indicating that these are preferred components of the encompassed compositions. Further claim 7 gives no amounts or ratios therefore it encompasses ingredients in amounts not encompassed by the disclosed Declarations. These amounts would include polyethylene glycol 4000 in an amount of .05% and there appears to be no evidence to support that Applicant's alleged unexpected results would occur when PEG 4000 is in this amount. Applicant has failed to show that these alleged unexpected results will occur in mixtures of all different amounts of each component that Applicant asserts is essential.

Declaration filed under 1.132

It is asserted that the amount of each component and the concentration of sample 7 & 8 are described in Paragraph 5 and 6 of the declaration. For the excess of PEG 4000, the ratio of PEG 4000 and PG in sample 4 was erroneously described as 3:1 and actually was 1:3. Thus, no excess amount of PEG 4000 was used. As for the result of a sample comprising only PEG400 and PEG4000, since viscosity of the PEG400 is too low and the viscosity of PEG4000 is too high to use for solo base material, there would be no efficacy. Lastly, with regards to the initial appearance of the teeth, as the teeth never have a red color before, it is not necessary to compare before and after adding red food coloring. The Declaration discloses the red coloring of sample 7 migrated 9.0 mm and the red coloring of sample 8 (instantly claimed sample) migrated 18.0 mm. This was unexpected considering poor penetrability of PEG 600 alone. Thus, it appears that the base including PEG 400, PEG 600, PEG 4000, and PG of the

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claimed composition possesses superior penetrability. Therefore, even if *prima facie* case of obviousness were established, the unexpected result would rebut any such case. Applicant respectfully submits Claim 7, is allowable over the cited reference.

Examiner's Response to Declaration

The Declaration is insufficient to overcome the rejection. In regard to samples of PEG 400 and PEG 4000 not having efficacy, Applicant has not supported this statement with any evidence. It is noted Applicant has tested water, which would appear to have a lower or at least the same viscosity as PEG 400. Thus it does not appear that a sample comprising only PEG 400 could not be made as inferred by Declarant. In regard to PEG 4000 having a viscosity that is too high, the viscosity could have been lowered when using water as a solvent since it appears the experiments use water as a comparison (Sample No. 1) and PEG 4000 appears to always be in a mixture with an ingredient of a lower viscosity. Further since it appears Declarant is asserting PEG 4000 is a critical component (a required component in the base, page 2, paragraph one of second Declaration), a sample comprising PEG 4000 in a solvent such as water would help determine if the results obtained by Declarant are additive or unexpected as alleged by Declarant.

In regard to Experiment 2, it does appear that the mixture of PEG 4000, PEG 400, PEG 600 and propylene glycol (sample 8) does have a better effect than the mixture of PEG 4000, PEG 400 and propylene glycol (sample 7). It is not however, clear

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if this better result is additive or unexpected, based on the addition of PEG 600. The disclosure of sample 5 does not provide an adequate comparison because it appears both sets of experiments are under different conditions because sample 3 gives different results from sample 7, and these appear to be similar samples comprising PEG 400, PEG 4000 and propylene glycol.

Even if, for *arguendo*, the results disclosed by the declaration were concluded to be unexpected, the results are not commensurate in scope with the instant claims. Although Declarant asserts that the amount PEG 4000 is not important, it has not been shown that the alleged unexpected results are obtained from any amount of PEG 4000. Further it appears that the Declarant asserts that PEG 4000 is an essential component and therefore it would appear that the amount would actually be critical to the results.

Claims 7 and 8 are rejected.

Claim 1-6 and 13-16 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

/Lezah W Roberts/
Examiner, Art Unit 1612